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| APPLICATION NO.                                                           | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---------------------------------------------------------------------------|-------------|----------------------|---------------------|------------------|
| 09/977,358                                                                | 10/16/2001  | Rembert Pieper       | 42521               | 3368             |
| 24280                                                                     | 7590        | 08/22/2005           | EXAMINER            |                  |
| CHOATE, HALL & STEWART LLP<br>TWO INTERNATIONAL PLACE<br>BOSTON, MA 02110 |             |                      | VENCI, DAVID J      |                  |
|                                                                           |             |                      | ART UNIT            | PAPER NUMBER     |
|                                                                           |             |                      | 1641                |                  |

DATE MAILED: 08/22/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                 |               |   |
|------------------------------|-----------------|---------------|---|
| <b>Office Action Summary</b> | Application No. | Applicant(s)  | 3 |
|                              | 09/977,358      | PIEPER ET AL. |   |
|                              | Examiner        | Art Unit      |   |
|                              | David J. Venci  | 1641          |   |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on July 8, 2005.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 32,52,62-69,84,85,88,89 and 104-107 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 32,52,62-69,84,85,88,89 and 104-107 is/are rejected.
- 7) Claim(s) 53-61 is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on July 8, 2005 is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:
1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |                                                                                                                                               |                                                                             |
|-----------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                                                   | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                                          | Paper No(s)/Mail Date. _____                                                |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>07/08/05</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
|                                                                                                                                               | 6) <input type="checkbox"/> Other: _____                                    |

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## DETAILED ACTION

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on July 8, 2005, has been entered.

Currently, claims 32, 52, 62-69, 84-85, 88-89 and 104-107 are under examination.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

### ***Oath/Declaration***

The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02. The oath or declaration is defective because:

It does not identify the mailing address of each inventor. A mailing address is an address at which an inventor customarily receives his or her mail and may be either a home or business address. The mailing address should include the ZIP Code designation. The mailing address may be provided in an application data sheet or a supplemental oath or declaration. See 37 CFR 1.63(c) and 37 CFR 1.76.

It does not identify the U.S. provisional application on which priority is claimed.

***Drawings***

Drawings were received on July 8, 2005. These drawings are objected to because the gels depicted in Fig. 3(A), Fig. 3(B), Fig. 4(A), and Fig. 4(B) have poor resolution or perhaps too much protein. Specifically, Fig. 3(A), Fig. 3(B), Fig. 4(A), and Fig. 4(B) appear as solid black rectangles (with the exception of a few distinct white arrows in Fig. 3(A) and Fig. 3(B), which appear to point to areas of black within solid black rectangles).

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

***Claim Objections***

Claims 53-61 are objected to because the statuses of said claims are not identified. Applicants' reply filed July 8, 2005, alludes to the possibility that claims 53-61 are cancelled. Appropriate correction is required.

***Claim Rejections - 35 USC § 102***

Claims 32, 52, 62-69, 84, 89 and 104 are rejected under 35 U.S.C. 102(b) as being anticipated by Brian et al., 391 FEBS LETTERS 71 (1996).

Brian et al. describe a method for separating proteins (see Fig. 1, "scFv antibody library") from a sample that contains proteins (see p. 72, col. 1, third paragraph, "cytosolic cell extracts") and recovering a modified sample (see Abstract, "enrich selectively phage displayed antibodies directed against proteins constituting a difference between two populations of cells") comprising the steps of: removing (see p. 72, col. 1, fifth paragraph, "immunobead was washed", see Fig. 2(A), MIX+LDH versus MIX) at least two specific predefined proteins (see p. 73, col. 2, second paragraph, "Competitive proteins were... also added in solution", see Fig. 2(A), MIX+LDH versus MIX), recovering the modified sample (see Abstract, "enrich selectively phage displayed antibodies directed against proteins constituting a difference between two populations of cells"), wherein the removing step comprises contacting the sample with an affinity binding composition (see Fig. 1, "two solid phase system") comprising a first and second solid phase matrix (see Fig. 1, "two solid phase system") contacting each other (see Fig. 1, "immunobeads in an immunotube"), wherein each solid phase matrix comprises a plurality of particles (see Fig. 1, "immunobeads in an immunotube"), wherein the particles are present in a mixture (see p. 72, col. 1, sixth paragraph, "4 ml 2% MPBS... five immunobeads... were added"), a first receptor (see Fig. 1, "LDH") immobilized on said first solid phase matrix (see Fig. 1, "immunobeads"), and a second receptor (see Fig. 1, "MIX proteins") immobilized on said second solid phase matrix (see Fig. 1, "immunotube").

With respect to claims 64-69, Brian et al. describe a method wherein "different coating conditions in parallel" is performed "to cover as many proteins as possible" (see p. 74, col. 2, second full paragraph, last sentence).

Claims 32, 52, 62-69, 84-85, 88-89 and 104 are rejected under 35 U.S.C. 102(b) as being anticipated by Rubenstein (US 5,879,881).

Rubenstein describes a method for separating proteins (see Abstract, "capturing a target ligand") from a sample that contains proteins (see col. 8, line 67, "serum, plasma") and recovering a modified sample (see Fig. 6, "second absorbent member 38") comprising the steps of: removing at least two specific predefined proteins (see col. 5, line 53 to col. 6, line 2), recovering the modified sample (see Fig. 6, "second absorbent member 38"), wherein the removing step comprises contacting the sample with an affinity binding composition comprising a first and second solid phase matrix contacting each other, wherein each solid phase matrix comprises a plurality of particles, wherein the particles are present in a mixture, a first receptor immobilized on said first solid phase matrix, and a second receptor immobilized on said second solid phase matrix (see col. 5, line 53 to col. 6, line 2).

With respect to claim 85, Rubenstein describes a column (see Fig. 6) having a fluid inlet (see Fig. 6, "first porous member 14") and a fluid outlet (see Fig. 6, "second absorbent member 38").

#### ***Claim Rejections - 35 USC § 103***

Claims 32, 52, 62-69, 84-85, 88-89 and 104-107 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ullman et al. (US 5,137,808) in view of Rubenstein (US 5,879,881).

Ullman et al. describe a method for separating proteins (see Abstract, "capturing a member of a specific binding pair") from a sample (see col. 17, lines 17-21) and recovering a modified sample (see Fig. 1A,

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"absorbent means 20"; see col. 16, lines 29-32) comprising the steps of: removing at least two specific predefined proteins (see col. 20, lines 32-44) recovering the modified sample (see Fig. 1A, "absorbent means 20"; see col. 16, lines 29-32), wherein the removing step comprises contacting the sample with an affinity binding composition (see Fig. 1A, "immunosorbing zone 84").

Ullman et al. do not describe "a first and second solid phase matrix contacting each other, wherein each solid phase matrix comprises a plurality of particles, and wherein the particles of the first and second solid phase matrices are present as a mixture" (claim 63). Ullman et al. do not describe "a plurality of solid phase matrices arranged such that each solid phase matrix is in contact with at least one other solid phase matrix; and a plurality of receptors having different protein binding specificities, wherein the receptors are immobilized on the plurality of solid phase matrices such that each solid phase matrix has a different protein binding specificity, wherein each solid phase matrix comprises a plurality of particles, and wherein the particles are present in the affinity binding composition as a mixture" (claim 84).

However, Rubenstein describes an affinity binding composition comprising a first and second solid phase matrix contacting each other, wherein each solid phase matrix comprises a plurality of particles, wherein the particles are present in a mixture, a first receptor immobilized on said first solid phase matrix, and a second receptor immobilized on said second solid phase matrix (see col. 5, line 53 to col. 6, line 2).

Therefore, it would have been obvious for a person of ordinary skill in the art to replace the affinity binding composition of Ullman et al. with an affinity binding composition comprising a plurality of particles because Rubenstein discovered that particle-based compositions "may enhance the contact between receptor bound to the microspheres and the target ligand and permit effective washing during an assay process" (see col. 5, lines 20-24). According to Rubenstein, persons of ordinary skill would have a reasonable expectation of success because "Techniques for the coating or covalent binding of proteins to microspheres... are well known to the art" (see col. 4, lines 59-61).

***Response to Arguments***

In prior Office Action, claims 27-42, 44-62, 98-105 and 108-109 were rejected under 35 USC 102(e) as being anticipated by Hutchens & Yip (US 6,225,047). In response, Applicants have cancelled independent claim 27. Accordingly, this rejection is withdrawn.

In prior Office Action, claims 63-97 were rejected under 35 USC 102(e) as being anticipated by Mehta et al. (US 6,632,655). In response, Applicants have amended independent claims 63 and 84 to add the limitations of "proteins". Examiner observes that Mehta et al. do not appear to teach the step of "producing a modified sample" or "recovering the modified sample" containing a plurality of proteins, as recited in both claims 63 and 84. This rejection is withdrawn solely because Applicants have amended independent claims 63 and 84 to add the limitations of "proteins".

Examiner's objection to Applicants' declaration is maintained for the reasons set forth in the prior Office Action.

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***Conclusion***

No claims are allowed at this time.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David J. Venci whose telephone number is 571-272-2879. The examiner can normally be reached on 08:00 - 16:30 (EST). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

David J Venci  
Examiner  
Art Unit 1641

djv

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*08/17/05*